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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,834	10/25/2001	Satoshi Kudo	01670/HG	8652

1933 7590 09/24/2004

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,834	KUDO ET AL.	
	Examiner	Art Unit	
	Lakshmi S Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-26-04 has been entered.

Claims 1-9, and 13-17 are pending.

Claim Rejections - 35 USC § 112

Claims 3, 4, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating obesity, does not reasonably provide enablement for preventing obesity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability of the art, and the working examples. All the factors have been considered with regard to the claim, with the most relevant factors discussed below.

Nature of the Invention and Breadth of Claims: All rejected claims recite a method of improving lipid metabolism, method of treating or preventing obesity, prophylaxis or therapeutic treatment of hyperlipidemia in an animal comprising orally administering to the animal a physiologically effective amount of a conjugated fatty acid ester containing conjugated fatty acid

with conjugated double bonds within the molecule. Thus, the instant claim encompasses treatment as well as prevention of lipid related diseases, disorders as well as obesity.

State of the Art: The state of the art does recognize the administration of instant conjugated fatty acid ester, particularly, conjugated linoleic acid ester to treat hyperlipidemia, treating over weight, atherosclerosis etc., as also acknowledged by applicants in the instant specification, but does not recognize a complete prevention of obesity. Further, the state of the art also recognize that obesity is caused by various factors such as hyperlipidemia, dietary glycemic index, a Polymorphic leptin receptor gene etc., and also dietary factors themselves such as fiber content, palatability, and energy density etc (see attached references of Ross et al, J. Clin. Oncol. 2004 & Adam et al Proc. Nutr. Soc. 2004). The state of the art recognizes the effect of food consumption on obesity but does not suggest a complete prevention of obesity with a single compound.

Guidance, predictability and experimentation: Instant specification provides an example showing the effect of instant claimed compound on the feed intake and organ fat deposition over a period of 7 weeks. Mice fed with the inventive compound exhibited less feed intake and lower body weight compared to the mice fed on diet containing other oils. Thus, applicants have only provided evidence that instant compound reduces weight gain over a short period of time, which is different from developing obesity over a long period of time. In the absence of working examples or detailed guidance in the specification, one of an ordinary skill in the art is uncertain regarding the use of the claimed compound for a complete prevention of obesity (caused by several factors). Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. For the reasons set forth it appears that undue experimentation would be required of

one skilled in the art to practice the claimed invention using the guidance provided in the instant specification.

For examination purposes, the phrase "preventing" is interpreted as "treating" the instant conditions.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 102

Claims 1, 2 and 9, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,177,580 to Timmerman et al ('580).

'580 discloses a process of making synthetic triglycerides esters by reacting a glycerol with a fatty acid mixture containing at least 50% by weight, based on the weight of the fatty acid mixture, of conjugated linoleic acid so as to form a glycerides. '580 describes conjugated linoleic acids as those distinguished from other fatty acids by the presence of double bonds at carbon atoms 9 and 11, 10 and 12 and 11 and 13 (col. 1, lines 11-16), and thus meet the claim 1 requirement that the conjugated fatty acid contains internal double bonds. With respect to the percentage of triglycerides claimed, '580 disclose that upon esterification of glycerol with conjugated linoleic acid, the resulting product contains 80 to 98% triglycerides content (also table 3 shows the % of mono-, di- and triglycerides of the glycerides). In particular, '580 disclose conjugated linoleic acid as a 9,11-octadecandienoic acid and 10, 12-octadecandienoic acids (col. 3, lines 52-56). Thus, '580 anticipate instant claims.

Claim Rejections - 35 USC § 103

Claims 1-9 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,554,646 to Cook et al ('646) in view of US 6,177,580 to Timmerman et al ('580).

'646 teaches a method of reducing body fat and a method of preventing loss of protein using compositions containing conjugated linolenic acid (CLA, col. 1, lines 16-60 and col. 2, example 3). '646 suggest administering CLA as pharmaceutical or veterinary compositions such as tablets, capsule, food supplement etc (col. 3, lines 60-67 and col. 4, lines 1-5). '646 teach conjugated fatty acid but not glycerides of conjugated fatty acid as claimed.

'580 discloses a process of making synthetic triglycerides esters by reacting a glycerol with a fatty acid mixture containing at least 50% by weight, based on the weight of the fatty acid mixture, of conjugated linoleic acid so as to form a glycerides. '580 teach that the above triglycerides are comparable with pure conjugated linoleic acid in antioxidant and color stabilizing effects when used in foods. '580 teaches that conjugated linoleic acid, normally used in food and pharmaceuticals, '580 also suggest using the above triglycerides in foods and pharmaceutical industry for organoleptic property and also since they can be readily incorporated in fat-containing foods (col.2). '580 suggest that the glycerides of their invention can be used in all areas in which conjugated fatty acids are used.

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to substitute conjugated linoleic acid of '646 with the conjugated linoleic acid based glyceride of '580 in controlling body fat (obesity) and hyperlipidemia because '580 suggest that the glycerides have properties comparable to CLA and in addition have better organoleptic

properties than CLA and hence a substitute for CLA. The expected result is to reduce the body fat and aid in dieting and also effectively reduce the fat content of meats. Further formulating the glycerides containing conjugated linoleic acid of '580 as a dietary supplement such as milk or as a pharmaceutical or nutritional supplement (such as tablet or a capsule etc) with an expectation to provide effective treatment for obesity would have been within the scope of a skilled artisan.

Response to Arguments

Applicants' arguments filed on 3-23-2004 have been fully considered but not found persuasive:

Timmerman ('580)-102(b) Rejection:

Applicants' argue that Timmermann et al. (USP 6,177,580) disclose a process for making synthetic triglycerides by esterification of glycerol with fatty acid mixture containing at least 50% by weight, based on the weight of the fatty acid mixture, of conjugated linoleic acid ("CLA") to form glyceride. It is argued Timmermann et also disclose that a glyceride prepared the process has composition of 95% of triglyceride of CLA, 3% of diglyceride of CLA and 2wt% of monoglyceride of CLA (see Example 3 column lines 30-35 of Timmermann et a1.). However, applicants argue that Timmermann et does not disclose that the content of CLA the CLA glyceride above Accordingly, the glyceride taught by Timmermann et al. differs from the conjugated fatty acid glyceride recited in the presently claimed invention. Applicants' arguments are not found persuasive because the process described by Timmermann is same as that claimed in the instant invention. Further, Timmermann clearly states that the triglycerides are tranesterified with fatty acid mixture containing at least 50% or more, especially 70% to 100%

by weight of CLA, more preferably 100% CLA (col. 4, lines 6-9 and lines 23-29). Thus, it is implicit that the content of CLA in the teachings of Timmerman meets the claimed requirements and that the conjugated fatty acid ester of Timmermann is not different from that of instant claims.

Timmermann and Cook et al:

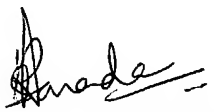
Applicants argue that examiner admits that Timmermann et al. fails to teach the method of treating obesity, improving lipid-treating hyperlipidemia as claimed by applicants and that the synthetic glyceride of Timmermann differs from the conjugated fatty acid glyceride of the present claimed invention. Further applicants argue that Timmermann fails to teach soybean milk, capsule or a tablet form, as recited in applicants' claims. Applicants argue that Cook et al. (USP 5,554,646) teach a method of reducing body fat and a method preventing the loss of protein using compositions ("CLA") containing only free CLAS or CLA salts, which have no relation to conjugated fatty acid glycerides (column 5, lines 14-20). Furthermore, applicants argue that Cook et al. teach the amount of CLA to be added to an animal's feed to reduce body fat can range from 0.01% to 2% or more by weight of the animal's or human's food, but not teach the use of CLA glycerides. Therefore, it is argued that it would not have been obvious for one of ordinary skill the art at the time the instant invention to use triglycerides containing more than 20% CLA to reduce body fat and hyperlipidemia, because Timmermann do not teach or suggest which the content of CLA is above 20wt%; glycerides (b) Cook et al discloses only free CLA and not CLA glycerides. Applicants' arguments have been fully considered but not found persuasive because as explained above, Timmermann does suggest CLA above 50% and even up to 100% by weight of the conjugate glyceride. Further, the motivation to replace CLA (free and

salt form) of Cook with the CLA glyceride of Timmermann comes from the teaching of latter that CLA glyceride does not have bitterness of CLA and is more organoleptic than its counterpart CLA (Cook) and thus imparts a pleasant taste to foods or pharmaceuticals. The motivation to combine the analogous teachings flows logically.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
September 22, 2004